

described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect may submit one or more applications for interim extensions for periods of up to one year each. The initial application for interim extension must be filed during the period beginning 6 months and ending 15 days before the patent term is due to expire. Each subsequent application for interim extension must be filed during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be entitled under 35 U.S.C. 156(c).

(b) A complete application for interim extension under this section shall include all of the information required for a formal application under § 1.740 and a complete application under § 1.741. Sections (a)(1), (a)(2), (a)(4), and (a)(6)–(a)(17) of § 1.740 and § 1.741 shall be read in the context of a product currently undergoing regulatory review. Sections (a)(3) and (a)(5) of § 1.740 are not applicable to an application for interim extension under this section.

(c) The content of each subsequent interim extension application may be limited to a request for a subsequent interim extension along with a statement that the regulatory review period has not been completed along with any materials or information required under §§ 1.740 and 1.741 that are not present in the preceding interim extension application.

[60 FR 25619, May 12, 1995]

§ 1.791 Termination of interim extension granted prior to regulatory approval of a product for commercial marketing or use.

Any interim extension granted under 35 U.S.C. 156(d)(5) terminates at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use. If within that 60-day period the patent owner or its agent files an application for extension under §§ 1.740 and 1.741 including any addi-

tional information required under 35 U.S.C. 156(d)(1) not contained in the application for interim extension, the patent shall be further extended in accordance with the provisions of 35 U.S.C. 156.

[60 FR 25619, May 12, 1995]

**Subpart G—Biotechnology
Invention Disclosures**

DEPOSIT OF BIOLOGICAL MATERIAL

SOURCE: 54 FR 34880, Aug. 22, 1989, unless otherwise noted.

§ 1.801 Biological material.

For the purposes of these regulations pertaining to the deposit of biological material for purposes of patents for inventions under 35 U.S.C. 101, the term biological material shall include material that is capable of self-replication either directly or indirectly. Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds. Viruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material.

§ 1.802 Need or opportunity to make a deposit.

(a) Where an invention is, or relies on, a biological material, the disclosure may include reference to a deposit of such biological material.

(b) Biological material need not be deposited unless access to such material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112. If a deposit is necessary, it shall be acceptable if made in accordance with these regulations. Biological material need not be deposited, inter alia, if it is known and readily available to the public or can be made or isolated without undue experimentation. Once deposited in a depository complying with these regulations, a biological material will be considered to be readily available even though some requirement of law or regulation of the United States or of the

§ 1.803

37 CFR Ch. I (7–1–08 Edition)

country in which the depository institution is located permits access to the material only under conditions imposed for safety, public health or similar reasons.

(c) The reference to a biological material in a specification disclosure or the actual deposit of such material by an applicant or patent owner does not create any presumption that such material is necessary to satisfy 35 U.S.C. 112 or that deposit in accordance with these regulations is or was required.

§ 1.803 Acceptable depository.

(a) A deposit shall be recognized for the purposes of these regulations if made in

(1) Any International Depositary Authority (IDA) as established under the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure, or

(2) Any other depository recognized to be suitable by the Office. Suitability will be determined by the Director on the basis of the administrative and technical competence, and agreement of the depository to comply with the terms and conditions applicable to deposits for patent purposes. The Director may seek the advice of impartial consultants on the suitability of a depository. The depository must:

- (i) Have a continuous existence;
- (ii) Exist independent of the control of the depositor;
- (iii) Possess the staff and facilities sufficient to examine the viability of a deposit and store the deposit in a manner which ensures that it is kept viable and uncontaminated;
- (iv) Provide for sufficient safety measures to minimize the risk of losing biological material deposited with it;
- (v) Be impartial and objective;
- (vi) Furnish samples of the deposited material in an expeditious and proper manner; and
- (vii) Promptly notify depositors of its inability to furnish samples, and the reasons why.

(b) A depository seeking status under paragraph (a)(2) of this section must direct a communication to the Director which shall:

(1) Indicate the name and address of the depository to which the communication relates;

(2) Contain detailed information as to the capacity of the depository to comply with the requirements of paragraph (a)(2) of this section, including information on its legal status, scientific standing, staff and facilities;

(3) Indicate that the depository intends to be available, for the purposes of deposit, to any depositor under these same conditions;

(4) Where the depository intends to accept for deposit only certain kinds of biological material, specify such kinds;

(5) Indicate the amount of any fees that the depository will, upon acquiring the status of suitable depository under paragraph (a)(2) of this section, charge for storage, viability statements and furnishings of samples of the deposit.

(c) A depository having status under paragraph (a)(2) of this section limited to certain kinds of biological material may extend such status to additional kinds of biological material by directing a communication to the Director in accordance with paragraph (b) of this section. If a previous communication under paragraph (b) of this section is of record, items in common with the previous communication may be incorporated by reference.

(d) Once a depository is recognized to be suitable by the Director or has defaulted or discontinued its performance under this section, notice thereof will be published in the Office Gazette of the Patent and Trademark Office.

§ 1.804 Time of making an original deposit.

(a) Whenever a biological material is specifically identified in an application for patent as filed, an original deposit thereof may be made at any time before filing the application for patent or, subject to § 1.809, during pendency of the application for patent.

(b) When the original deposit is made after the effective filing date of an application for patent, the applicant must promptly submit a statement